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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
[illegible]464,8[illegible]	12/[illegible]/99	BERCHTOLD P	P564-9049

HM12/0716

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EXAMINER	
LI,Q	
ART UNIT	**PAPER NUMBER**
1632	10

DATE MAILED: 07/16/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

PTO-90C (Rev.11/00)

1- File Copy

Office Action Summary	Application No.	Applicant(s)	
	09/424,840	BERCHTOLD ET AL.	
	Examiner	Art Unit	
	Janice Li	1632	

– The MAILING DATE f this communication appears on the cover sheet with the correspondence address –

Peri d f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-25 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-25 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claim Objections

Claims 19-22 are objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim cannot depend from any other multiple dependent claim. See MPEP § 608.01(n). However, these claims have been incorporated in groups of invention as they potentially read on in this Office action. Appropriate correction is required.

Election/Restrictions

1. This application contains the following inventions or groups of inventions, which are not so linked as to form a single inventive concept under PCT Rule 13.1. In order for all inventions to be examined, restriction is required.

I. Claims 1-3, 11, 12, 19-21 are drawn to a nucleic acid encoding the heavy chain of a human antiidotypic antibody, a vector containing the nucleic acid, a transformed host cell containing the vector, and a method of using the nucleic acids as a pharmaceutical composition, wherein the nucleic acid is selected from the group of sequences consisting of SEQ. ID No. 31-36 and/or combination thereof. Classified in class 514, subclass 44.

II. Claims 4-6, 11, 12, 19-21 are drawn to a nucleic acid encoding the light chain of a human antiidotypic antibody, a vector containing the nucleic acid, a transformed host cell containing the vector, and a method of using the nucleic acids as a pharmaceutical composition, wherein the nucleic acid is selected

from the group of sequences consisting of SEQ. ID No. 37-42 and/or combination thereof. Classified in class 514, subclass 44.

III. Claims 7-8, 11, 12, 19-21 are drawn to a nucleic acid encoding the heavy chain of a human autoantibody, a vector containing the nucleic acids, a transformed host cell containing the vector, and a method of using the nucleic acids as a pharmaceutical composition, wherein the nucleic acid is selected from the group of sequences consisting of SEQ. ID No. 43-51, and sequences recited in claim 8, and/or combination thereof. Classified in class 514, subclass 44.

IV. Claims 9-10, 11, 12, 19-21 are drawn to a nucleic acid encoding the light chain of a human autoantibody, a vector containing the nucleic acids, a transformed host cell containing the vector, and method of using such as a pharmaceutical composition, wherein the nucleic acid is selected from the group of sequences consisting of SEQ. ID No. 52, 53, and sequences recited in claim 10, and/or combination thereof. Classified in class 514, subclass 44.

V. Claims 13-16, 19-22 are drawn to a polypeptide encoded by a nucleic acid encoding the heavy chain of a human antiidotypic antibody, comprising a CR3 region, and further comprising a variable domain of the H Chain and/or/both of the L Chain; wherein the polypeptide is encoded by a nucleic acid sequence selected from the group of sequences consisting of SEQ. ID No. 31-36 and/or combination thereof. The claims are further directed to a method of using the

polypeptide as a pharmaceutical composition. Classified in class 424, subclass 93.1, and in class 435, subclass 375.

VI. Claims 13-16, 19-22 are drawn to a polypeptide encoded by a nucleic acid encoding the light chain of a human antiidotypic antibody, comprising a CR3 region, and further comprising a variable domain of the H Chain and/or/both of the L Chain; wherein the polypeptide is encoded by a nucleic acid sequence selected from the group of sequences consisting of SEQ. ID No. 37-42 and/or combination thereof. The claims are further directed to a method of using the polypeptide as a pharmaceutical composition. Classified in class 424, subclass 93.1, and in class 435, subclass 375.

VII. Claims 13-16, 19-22 are drawn to a polypeptide encoded by a nucleic acid encoding the heavy chain of a human autoantibody, comprising a CR3 region, and further comprising a variable domain of the H Chain and/or/both of the L Chain; wherein the polypeptide is encoded by a nucleic acid sequence selected from the group of sequences consisting of SEQ. ID No. 43-51, and sequences recited in claim 8, and/or combination thereof. The claims are further directed to a method of using the polypeptide as a pharmaceutical composition. Classified in class 424, subclass 93.1, and in class 435, subclass 375.

VIII. Claims 13-16, 19-22 are drawn to a polypeptide encoded by a nucleic acid encoding the light chain of a human autoantibody, comprising a CR3, and further comprising a variable domain of the H Chain and/or/both of the L

Chain; wherein the polypeptide is encoded by a nucleic acid sequence selected from the group of sequences consisting of SEQ. ID No. 52, 51, and sequences recited in claim 10, and/or combination thereof. The claims are further directed to a method of using the polypeptide as a pharmaceutical composition. Classified in class 424, subclass 93.1, and in class 435, subclass 375.

IX. Claims 17-22 are drawn to an antibody to a polypeptide and a method of using the antibody as a pharmaceutical composition. Classified in class 424, subclass 93.1, and in class 435, subclass 375.

X. Claims 23-25 are drawn to a process for isolating phagemid clones which express nucleic acids encoding an antibody against GPIIb/IIIa. Classified in class 424, subclass 93.1.

2. The inventions listed as groups do not relate to a single inventive concept under PCT Rule 13.1, because under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The International Search Report cites multiple prior arts of record, each anticipates different inventive groups of instant application, e.g. *Horn et al* anticipate claims 4-6 and 13-15 (groups II and VI), unity of invention is lacking.

Furthermore, these inventive groups are drawn to different products, i.e. nucleic acids, polypeptides, idiotypic antibodies, antoantibodies and antibodies recognizing the polypeptides. The different products have distinct chemical structure, different mode of

operation, different metabolic pathway, and different technical considerations. The different products are obtainable by different methods, e.g. autoantibodies are obtained from the serum of patients. The inventive groups further comprise methods of making or using the products. The methods have different method steps, and use materially different agents. Group X, drawn to a process for isolating phagemid clones, does not share the common inventive concept or special technical feature with groups I-IV, drawn to methods of using polynucleotide, unity of invention is lacking.

Applicants are advised to see 37 CFR 1.475 (a)-(d) for details. 37 CFR 1.475 (a) recites "An international and a national stage application shall related to one invention only or to a group of inventions so linked as to form a single general inventive concept ('requirement of unity of invention'). ..." 37 CFR 1.475 (b) does not provide for more than one product as a combination of invention.

3. This application contains claims directed to the following patentably distinct species of the claimed invention: Each of the inventive groups I-VIIII are further directed to composition claims reciting different combinations of individual nucleotide sequences. For example, Group III contains an antibody with a CR3 region encoded by a nucleic acid selected from a group of nucleotide sequences of SEQ. ID Nos.: 43-51, and it further contains multiple combinations of sequences, i.e. a nucleic acid encodes an antibody having both a CR3 and a CR1/or CR2 region, wherein the CR1/CR2 sequence is selected from the group of 31 sequences recited in claim 8. If invention I-VIIII is elected, further election of a species is necessary, i.e. elect a single sequence or a

single combination of sequences for examination. If applicants elect a sequence combination for examination, which contains ten or fewer sequences, all of the sequences of the combination will be searched. If the selected combination contains more than ten sequences, the combination will be searched until one nucleotide sequence is found to be allowable over the prior art. The order of searching will be chosen by the examiner to maximize the identification of a sequence allowable over the prior art. If no individual nucleotide sequence is found to be allowable, the examiner will consider whether the combination of sequences taken as a whole renders the claim allowable. The identification of any sequence(s) allowable over the prior art will cause all combinations containing the such sequence(s) to be allowable over the prior art. See 1192 O.G. 68 (Nov. 19, 1996).

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-22 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

4. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is advised that where a single claim encompasses more than one invention as defined above, upon election of an invention for examination, said claim will only be examined to the extent that it reads upon the elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen M Hauda can be reached on 703-305-6608. The fax numbers for the organization where this application or proceeding is assigned are 703-308-8724 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Kay Pinsky, whose telephone number is (703) 305-3553.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).

Q. Janice Li
Examiner
Art Unit 1632

ROBERT A. SCHWARTZMAN
PRIMARY EXAMINER